10-13-2017

Authorizes State Regulation of Kidney Dialysis Clinics. Establishes Minimum Staffing Requirements and Limits Charges for Patient Care. Initiative Statute.

17-0015 Amdt. # 1

By Hand Delivery

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INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

September 8, 2017

To: The Office of the Attorney General
Attn: Ashley Johansson, Initiative Coordinator
1300 "I" Street
Sacramento, CA 95814

Re: Submission of Amendment to the
Kidney Dialysis Patient Protection Act (No. 17-0015)

Dear Ms. Johansson:

On August 9, 2017 the proponents of a proposed statewide initiative titled "Kidney Dialysis Patient Protection Act" (the "Initiative") submitted a request that the Attorney General prepare a circulating title and summary pursuant to Article II, Section 10(d) of the California Constitution. Pursuant to Elections Code §9002(b), the proponents hereby submit timely amendments to the text of the Initiative. As the proponents of the Initiative, we approve the submission of the amended text to the Initiative and we declare that the amendments are reasonably germane to the theme, purpose, and subject of the Initiative. We request that the Attorney General prepare a circulating title and summary using the amended Initiative.

Please continue to direct all inquiries and correspondence regarding this proposed initiative to:

BJ Chisholm
Altshuler Berzon LLP
177 Post Street, Suite 300
San Francisco, CA 94108
Phone: 415-421-7151
Email: bchisholm@altber.com

Sincerely,

Edward Howard

Benjamen Tracey

Enclosure: Amended initiative language

This initiative measure is submitted to the people in accordance with the provisions of Article II, Section 8, of the California Constitution.

This initiative measure amends and adds sections to the Health and Safety Code; therefore, existing provisions proposed to be deleted are printed in ~~strikeout~~ type and new provisions proposed to be added are printed in *italic* type to indicate that they are new.

SEC. 1. Name

This act shall be known as the "Kidney Dialysis Patient Protection Act."

SEC. 2. Findings and Purposes

A. The People make the following findings:

(1) Kidney dialysis is a process where blood is cleaned of waste and excess water, usually through a machine outside the patient's body, and then returned to the patient. If someone who needs dialysis cannot obtain or afford high quality care, toxins build up in the body, leading to death.

(2) In California, at least 66,000 Californians undergo dialysis treatment.

(3) Just two multinational, for-profit corporations operate or manage nearly three-quarters of dialysis clinics in California and treat almost 70 percent of dialysis patients in California. These two multinational corporations annually earn billions of dollars from their dialysis operations, including almost $400 million each year in California alone.

(4) Because federal law mandates that private health insurance companies offer and pay for dialysis, private insurance companies have little ability to bargain with the two multinational dialysis corporations on behalf of their customers.

(5) Thus, for-profit dialysis corporations charge patients with private health insurance four times as much as they charge Medicare for the very same dialysis treatment, resulting in vast profits.

(6) In a market dominated by just two multinational corporations, California must ensure that dialysis is fairly priced and affordable.

(7) Other states have taken steps to protect these very vulnerable patients from these two multinational corporations, including by enacting common sense protections such as minimum staffing requirements.

(8) Current staffing levels in dialysis clinics in California are possibly dangerous and are inadequate to protect patient health against avoidable deaths, hospitalizations, infections, and medication errors.

(9) Efforts to enact protections for kidney dialysis patients in California have been stymied in Sacramento by the dialysis corporations, which spent over $600,000 in just the first six months of 2017 to influence the California Legislature.

B. Purposes:

(1) It is the purpose of this Act to ensure that outpatient kidney dialysis clinics provide quality and affordable patient care to people suffering from end stage renal disease.

(2) This Act is intended to be budget neutral for the State to implement and administer.

SEC. 3. Section 1226.4 is added to the Health and Safety Code, to read:

1226.4 (a) Minimum staffing requirements.

(1) A chronic dialysis clinic shall ensure that the following minimum staffing ratios are met at all times that patients are receiving, or preparing to receive, direct clinic care:

(A) At least one nurse is providing direct clinic care for every eight patients. A nurse shall only count toward this ratio during time periods the nurse has no responsibilities other than direct clinic care. A nurse manager or charge nurse shall not count toward the nurse-to-patient ratio.

(B) At least one hemodialysis technician is providing direct clinic care for every three patients. A hemodialysis technician shall only count toward this ratio during time periods the hemodialysis technician has no responsibilities other than direct clinic care. Hemodialysis technician trainees shall not count toward this ratio. Nurses counted toward the nurse-to-patient ratio shall not count toward the hemodialysis technician-to-patient ratio.

(2) A chronic dialysis clinic shall ensure that no more than 75 patients per full-time equivalent schedule are assigned at any time to any individual social worker and to any individual registered dietitian, regardless of the location where patient care is provided.

(3) The ratios described in paragraphs (1) and (2) shall constitute the minimum number of nurses, hemodialysis technicians, social workers, and registered dietitians assigned to patients. Additional nurses, hemodialysis technicians, social workers, and registered dietitians shall be assigned to the extent necessary to ensure that the staff-to-patient ratio is appropriate to the level of dialysis care given and meets the needs of patients.

(4) A chronic dialysis clinic shall ensure that the transition time between patients at a treatment station is no shorter than 45 minutes, provided that the department may by regulation set a minimum transition time other than 45 minutes if such modification is supported by changes in available clinical evidence regarding minimum transition times necessary to ensure safety and hygiene protocols in chronic dialysis clinics, including but not limited to changes in recommendations from the Centers for Disease Control and Prevention regarding standard hygiene practices.

(5) The requirements of this subdivision shall take effect on March 31, 2019.

(b) Inspections for safety and hygiene.

The department shall inspect each chronic dialysis clinic for which a license has been issued at least once per year, and shall conduct such inspections as often as necessary to ensure the existence of and compliance with adequate hygiene and sanitation protocols, compliance with this chapter, and the adequacy of the quality of care being provided.

(c) Licensing, recordkeeping, and reporting.

(1) It shall be a condition of licensure that a chronic dialysis clinic comply with this section, and the department shall not renew, transfer, or extend any license issued to a chronic dialysis clinic except upon a showing that the chronic dialysis clinic complies with the requirements of subdivision (a). The department shall not issue a license to any new chronic dialysis clinic unless that chronic dialysis clinic demonstrates the ability and intention to comply with the requirements of subdivision (a).

(2) Every chronic dialysis clinic for which a license has been issued shall maintain, and provide to the department on a form prescribed by the department, at a minimum, the following information:

(A) Actual staffing ratio and transition time data for the period covered by the submission, which shall include, at a minimum, daily totals of the total number and actual hours worked by nurses and hemodialysis technicians; the total number of patients and actual hours receiving direct clinic care; the daily average transition time for each treatment station; and, for each week, the total number of full-time equivalent social workers and registered dietitians and the total number of patients assigned to social workers and registered dietitians.

(B) Every instance, no matter how brief, during the period covered by the submission when staffing ratios or transition times did not satisfy the requirements of subdivision (a), and the reasons and circumstances therefor.

(3) The chief executive officer or administrator of the chronic dialysis clinic shall certify under penalty of perjury that he or she is satisfied, after review, that all information submitted pursuant to paragraph (2) is accurate and complete.

(4) The chronic dialysis clinic shall periodically submit such information described in paragraph (2) to the department on a schedule and in a format prescribed by the department, provided that the clinic shall submit that information no less frequently than four times per year.

(d) Complaints and patient rights.

(1) Within 60 days of receiving a complaint from a patient, an association of patients, a family member of a patient, an employee, an association of employees, a vendor, or a contractor of a chronic dialysis clinic that the chronic dialysis clinic has violated any requirement of this chapter, the department shall investigate the chronic dialysis clinic and, if the evidence shows a violation has occurred, the department shall impose discipline pursuant to Section 1240.1.

(2) To ensure that all health care workers of chronic dialysis clinics are entitled to whistleblower protections, Section 1278.5 shall apply to chronic dialysis clinics, and to the

extent of that application, references in Section 1278.5 to a health facility shall be deemed to be references to a chronic dialysis clinic, subject to paragraph (3).

(3) Notwithstanding Section 1417.2, moneys collected under paragraph (3) of subdivision (b) of Section 1278.5 from a chronic dialysis clinic shall be distributed to the department to implement and enforce laws governing chronic dialysis clinics.

(e) Protection of confidential information.

(1) The department shall redact from any writing, record, or document submitted or created pursuant to this section that is a public record within the meaning of subdivision (e) of Section 6252 of the Government Code all personal identifying or confidential information associated with any patients, to the extent required to prevent an unwarranted invasion of personal privacy, as that term is used in subdivision (c) of Section 6254 of the Government Code, but the department shall not withhold any such writing, record, or document in its entirety under subdivision (c) of Section 6254 of the Government Code.

(2) Information required to be submitted under subdivision (c), and complaints submitted under subdivision (d), shall not be withheld on the basis of subdivision (f) of Section 6254 of the Government Code.

(f) Definitions.

For purposes of this section:

(1) "Administrator" means the administrator as that term is used in Section 494.180(a) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(2) "At all times" includes times during which clinic personnel, including but not limited to nurses or hemodialysis technicians, are provided meal periods and rest or other breaks. No clinic personnel may be counted toward the required ratios during times they are taking such breaks or meal periods.

(3) "Charge nurse" means a charge nurse as described in Section 494.140(b)(3) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(4) "Chief executive officer" means the chief executive officer as that term is used in Section 494.180(a) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(5) "Direct clinic care" means initiating and discontinuing dialysis, monitoring patients during treatment, and administering medications, and physical presence in the immediate area where patients are dialyzed.

(6) "Full-time equivalent" means employment by a chronic dialysis clinic for 2,080 hours of work in 12 consecutive months.

(7) "Nurse" means a registered nurse licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code.

(8) "Nurse manager" means a nurse manager as described in Section 494.140(b)(1) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(9) "Registered dietitian" means a dietitian as described in Section 494.140(c) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(10) "Social worker" means a social worker as described in Section 494.140(d) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(11) "Hemodialysis technician" means a person who holds both of the following qualifications:

(A) The person is a patient care dialysis technician, as described in Section 494.140(e) of Title 42 of the Code of Federal Regulations as it read on December 31, 2016.

(B) The person is a Certified Hemodialysis Technician certified pursuant to Article 3.5 (commencing with Section 1247) of Chapter 3 of Division 2 of the Business and Professions Code.

(12) "Hemodialysis technician trainee" means a person who is undergoing training to become a hemodialysis technician, but who has not yet been certified as a Certified Hemodialysis Technician pursuant to Article 3.5 (commencing with Section 1247) of Chapter 3 of Division 2 of the Business and Professions Code.

(13) "Transition time" means the period of time beginning when one patient leaves a treatment station and ending when the next patient is placed in the treatment station, but does not mean the period of time after the last patient of the day leaves the treatment station.

(14) "Treatment station" means a physical location within a chronic dialysis clinic where an individual patient is dialyzed.

SEC. 4. Section 1240.1 is added to the Health and Safety Code, to read:

1240.1 (a) The department may assess an administrative penalty against a chronic dialysis clinic for a violation of this chapter. Each penalty issued pursuant to this chapter shall be classified as a major violation, an intermediate violation, or a minor violation based on the nature of the violation and the threat of harm to patients. A major violation shall be subject to an administrative penalty of up to one hundred thousand dollars ($100,000), an intermediate violation shall be subject to an administrative penalty of up to twenty thousand dollars ($20,000), and a minor violation shall be subject to an administrative penalty of up to two thousand dollars ($2,000).

(b) The department shall promulgate regulations establishing the criteria to assess an administrative penalty against a chronic dialysis clinic, which shall include, but not be limited to, consideration of all of the following:

(1) The probability and severity of the risk that the violation presents to the patient.

(2) The actual harm to patients, if any.

(3) The nature, scope, and severity of the violation.

(4) The chronic dialysis clinic's history of compliance with related state and federal statutes and regulations, including, but not limited to, the similarity in circumstances of the violation to any previous violation by the chronic dialysis clinic within a 24-month period.

(5) Factors beyond the control of the chronic dialysis clinic that restrict its ability to comply with this chapter or the rules and regulations promulgated thereunder.

(6) The demonstrated willfulness of the violation.

(7) The extent to which the chronic dialysis clinic detected the violation and took immediate action to correct the violation and to prevent that type of violation from recurring.

(c) If a chronic dialysis clinic disputes a determination by the department regarding an alleged deficiency or failure to correct a deficiency, or the reasonableness of a proposed deadline for correction of a violation or an amount of an administrative penalty, the chronic dialysis clinic may, within 10 working days, request a hearing pursuant to Section 131071. A chronic dialysis clinic shall pay all administrative penalties when all appeals have been exhausted and the department's position has been upheld.

(d) For purposes of Article 9 (commencing with Section 12650) of Chapter 6 of Part 2 of Division 3 of Title 2 of the Government Code, the information required to be provided under subdivision (c) of Section 1226.4 shall be deemed material to any claim for payment submitted by a chronic dialysis clinic within twelve months of the submission of information.

SEC. 5. Section 1240.2 is added to the Health and Safety Code, to read:

1240.2. (a) Subject to subdivision (d), prior to the effective date of regulations adopted to implement Section 1240.1, if a chronic dialysis clinic receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty of up to one hundred thousand dollars ($100,000). In determining the amount of the penalty, the department shall consider the severity and duration of the immediate jeopardy and the extent to which the conduct causing the immediate jeopardy could have been avoided.

(b) If a licensee disputes a determination by the department regarding an alleged deficiency or the alleged failure to correct a deficiency, or regarding the reasonableness of the proposed deadline for correction or the amount of the penalty, the licensee may, within 10 days, request an administrative hearing pursuant to Section 131071. Penalties shall be paid when appeals have been exhausted and if the department's position has been upheld.

(c) For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to one or more patients.

(d) This section shall only apply to incidents occurring on or after January 1, 2019, except that this section shall only apply to violations of subdivision (a) of Section 1226.4 occurring on or after March 31, 2019.

(e) Notwithstanding Section 11 of the act that added this section, new regulations are not required or authorized for implementation of this section.

(f) This section shall become inoperative on the effective date of regulations promulgated by the department pursuant to Section 1240.1.

SEC. 6. Section 1226.7 is added to the Health and Safety Code, to read:

1226.7. (a) Reasonable limits on charges for patient care by chronic dialysis clinics; rebates of amounts charged in excess of fair treatment payment amount.

(1) For purposes of this section, the "fair treatment payment amount" shall be an amount equal to 115 percent of the sum of all direct patient care services costs and all health care quality improvement costs incurred by a governing entity and its chronic dialysis clinics.

(2) For each fiscal year starting on or after January 1, 2019, a governing entity or its chronic dialysis clinics shall annually issue rebates to payers as follows:

(A) The governing entity shall calculate the "unfair excess charged amount," which shall be the amount, if any, by which treatment revenue from treatments provided by all of the governing entity's chronic dialysis clinics exceeds the fair treatment payment amount.

(B) The governing entity or its chronic dialysis clinics shall, on a pro rata basis based on the amounts paid and reasonably estimated to be paid, as those amounts are included in treatment revenue, issue rebates to payers (other than Medicare or other federal, state, county, city, or local government payers) in amounts that total the unfair excess charged amount.

(C) The governing entity or chronic dialysis clinic shall issue any rebates required by this section no less than 90 days and no more than 210 days after the end of its fiscal year to which the rebate relates.

(D) Where, in any fiscal year, the rebate the governing entity or chronic dialysis clinic must issue to a single payer is less than twenty dollars ($20), the governing entity or chronic dialysis clinic shall not issue that rebate, and shall provide to other payers in accordance with subparagraph (B) the total amount of rebates not issued pursuant to this subparagraph.

(E) For each fiscal year starting on or after January 1, 2020, any rebate issued to a payer shall be issued together with interest thereon at the rate of interest specified in subdivision (b) of Section 3289 of the Civil Code, which shall accrue from the date of payment by the payer.

(3) For each fiscal year starting on or after January 1, 2019, a governing entity shall maintain and provide to the department, on a form and schedule prescribed by the department, a report of all rebates issued under paragraph (2), including a description of each instance during the

period covered by the submission when the rebate required under paragraph (2) was not timely issued in full, and the reasons and circumstances therefor. The chief executive officer or principal officer of the governing entity shall certify under penalty of perjury that he or she is satisfied, after review, that all information submitted to the department under this paragraph is accurate and complete.

(4) In the event a governing entity or its chronic dialysis clinic is required to issue a rebate under this section, no later than 210 days after the end of its fiscal year the governing entity shall pay a penalty to the department in an amount equal to five percent of the unfair excess charged amount, provided that the penalty shall not exceed one hundred thousand dollars ($100,000). Penalties collected pursuant to this paragraph shall be used by the department to implement and enforce laws governing chronic dialysis clinics.

(5) If a chronic dialysis clinic or governing entity disputes a determination by the department to assess a penalty pursuant to this subdivision or subdivision (b), or the amount of an administrative penalty, the chronic dialysis clinic or governing entity may, within 10 working days, request a hearing pursuant to Section 131071. A chronic dialysis clinic or governing entity shall pay all administrative penalties when all appeals have been exhausted and the department's position has been upheld.

(6) If a governing entity or chronic dialysis clinic proves in any court action that application of this section to the chronic dialysis clinic or governing entity will, in any particular fiscal year, violate due process or effect a taking of private property requiring just compensation under the Constitution of this State or the Constitution of the United States, the provision at issue shall apply to the governing entity or chronic dialysis clinic, except that as to the fiscal year in question the number "115" whenever it appears in the provision at issue shall be replaced by the lowest possible whole number such that application of the provision to the governing entity or chronic dialysis clinic will not violate due process or effect a taking of private property requiring just compensation. In any civil action, the burden shall be on the governing entity or chronic dialysis clinic to propose a replacement number and to prove that replacing "115" with any whole number lower than the proposed replacement number would, for the fiscal year in question, violate due process or effect a taking of private property requiring just compensation.

(b) Compliance reporting by chronic dialysis clinics.

(1) For each fiscal year starting on or after January 1, 2019, a governing entity shall maintain and submit to the department a report concerning the following information for all of the chronic dialysis clinics the governing entity owns or operates in California—

(A) the number of treatments performed;

(B) direct patient care services costs;

(C) health care quality improvement costs;

(D) treatment revenue, including the difference between amounts billed but not yet paid and estimated realizable revenue;

(E) the fair treatment payment amount;

(F) the unfair excess charged amount;

(G) the amount, if any, of each payer's rebate, provided that any individual patient shall be identified using only a unique identifier that does not reveal the patient's name or identity; and

(H) a list of payers to whom no rebate was issued pursuant to subparagraph (D) of paragraph (2) of subdivision (a) and the amount not issued, provided that any individual patient shall be identified using only a unique identifier that does not reveal the patient's name or identity.

(2) The information required to be maintained and the report required to be submitted by this subdivision shall each be independently audited by a certified public accountant in accordance with the standards of the Accounting Standards Board of the American Institute of Certified Public Accountants, and shall include the opinion of that certified public accountant as to whether the information contained in the report fully and accurately describes, in accordance with generally accepted accounting principles in the United States, the information required to be reported under paragraph (1).

(3) The governing entity shall annually submit the report required by this subdivision to the department on a schedule, in a format, and on a form prescribed by the department, provided that the governing entity shall submit the information no later than 210 days after the end of its fiscal year. The chief executive officer or other principal officer of the governing entity shall certify under penalty of perjury that he or she is satisfied, after review, that the report submitted to the department under paragraph (1) is accurate and complete.

(4) In the event the department determines that a chronic dialysis clinic or governing entity failed to maintain the information or timely submit a report required under paragraph (1) of this subdivision or paragraph (3) of subdivision (a), or that the amounts or percentages reported by the chronic dialysis clinic or governing entity under paragraph (1) of this subdivision were inaccurate or incomplete, or that any failure by a chronic dialysis clinic or governing entity to timely issue in full a rebate required by subdivision (a) was not substantially justified, the department shall assess a penalty against the chronic dialysis clinic or governing entity not to exceed one hundred thousand dollars ($100,000). The department shall determine the amount of the penalty based on the severity of the violation, the materiality of the inaccuracy or omitted information, and the strength of the explanation, if any, for the violation. Penalties collected pursuant to this paragraph shall be used by the department to implement and enforce laws governing chronic dialysis clinics.

(c) Definitions.

For purposes of this section:

(1) "Direct patient care services costs" means those costs directly associated with operating a chronic dialysis clinic in California and providing care to patients in California. Direct patient care services costs shall include, regardless of the location where each patient undergoes dialysis, only (i) salaries, wages, and benefits of non-managerial chronic dialysis clinic staff,

including all clinic personnel who furnish direct care to dialysis patients, regardless of whether the salaries, wages, or benefits are paid directly by the chronic dialysis clinic or indirectly through an arrangement with an affiliated or unaffiliated third party, including but not limited to a governing entity, an independent staffing agency, a physician group, or a joint venture between a chronic dialysis clinic and a physician group; (ii) staff training and development; (iii) pharmaceuticals and medical supplies; (iv) facility costs, including rent, maintenance, and utilities; (v) laboratory testing; and (vi) depreciation and amortization of buildings, leasehold improvements, patient supplies, equipment, and information systems. For purposes of this section, "non-managerial chronic dialysis clinic staff" includes all clinic personnel who furnish direct care to dialysis patients, including nurses, technicians and trainees, social workers, registered dietitians, and non-managerial administrative staff, but excludes managerial staff such as facility administrators. Categories of direct patient care services costs may be further prescribed by the department through regulation.

(2) "Governing entity" means a person, firm, association, partnership, corporation, or other entity that owns or operates a chronic dialysis clinic for which a license has been issued, without respect to whether the person or entity itself directly holds that license.

(3) "Health care quality improvement costs" means costs, other than direct patient care services costs, that are related to the provision of care to chronic dialysis patients and that are actually expended for goods or services in California that are required to maintain, access or exchange electronic health information, to support health information technologies, to train non-managerial chronic dialysis clinic staff engaged in direct patient care, and to provide patient-centered education and counseling. Additional costs may be identified by the department through regulation, provided that such costs are actually spent on services offered at the chronic dialysis clinic to chronic dialysis patients and are spent on activities that are designed to improve health quality and to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(4) "Payer" means the person or persons who paid or are financially responsible for payments for a treatment provided to a particular patient, and may include the patient or other individuals, primary insurers, secondary insurers, and other entities, including Medicare and any other federal, state, county, city, or other local government payer.

(5) "Treatment" means each instance when the chronic dialysis clinic provides services to a patient.

(6) "Treatment revenue" for a particular fiscal year means all amounts actually received and estimated realizable revenue for treatments provided in that fiscal year. Estimated realizable revenue shall be calculated in accordance with generally accepted accounting principles, and shall be a reasonable estimate based on (i) contractual terms for patients covered under commercial healthcare plans with which the governing entity or clinics have formal agreements; (ii) revenue from Medicare, Medicaid, and Medi-Cal based on rates set by statute or regulation, and estimates of amounts ultimately collectible from government payers, commercial healthcare plan secondary coverage, patients, and other payers; and (iii) historical collection experience.

SEC. 7. Section 1226.8 is added to the Health and Safety Code, to read:

1226.8 (a) A chronic dialysis clinic shall not discriminate with respect to offering or providing care, and shall not refuse to offer or provide care, to patients on the basis of the payer for treatment provided to a patient, including but not limited to on the basis that the payer is a patient, private payer or insurer, Medi-Cal, Medicaid, or Medicare.

(b) A chronic dialysis clinic shall not terminate, abridge, modify, or fail to perform under any agreement to provide services to patients covered by Medi-Cal, Medicaid, or Medicare on the basis of requirements imposed by this chapter.

SEC. 8. Section 1266.3 is added to the Health and Safety Code, to read:

1266.3. It is the intent of the People that California taxpayers not be financially responsible for implementation and enforcement of the Kidney Dialysis Patient Protection Act. In order to effectuate that intent, when calculating, assessing, and collecting fees imposed on chronic dialysis clinics pursuant to Section 1266, the department shall take into account all costs associated with implementing and enforcing Sections 1226.4, 1226.7, 1226.8, 1240.1, or 1240.2.

SEC. 9. Section 1228 of the Health and Safety Code is amended to read:

1228. (a) Except as provided in subdivision (c), every clinic for which a license or special permit has been issued shall be periodically inspected. ~~The~~ *Except as provided in Section 1226.4, the* frequency of inspections shall depend upon the type and complexity of the clinic or special service to be inspected. Inspections shall be conducted no less often than once every three years and as often as necessary to ensure the quality of care being provided.

(b) (1) During inspections, representatives of the department shall offer any advice and assistance to the clinic as they deem appropriate. The department may contract with local health departments for the assumption of any of the department's responsibilities under this chapter. In exercising this authority, the local health department shall conform to the requirements of this chapter and to the rules, regulations, and standards of the department.

(2) The department shall reimburse local health departments for services performed pursuant to this section, and these payments shall not exceed actual cost. Reports of each inspection shall be prepared by the representative conducting it upon forms prepared and furnished by the department and filed with the department.

(c) This section shall not apply to any of the following:

(1) A rural health clinic.

(2) A primary care clinic accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), or any other accrediting organization recognized by the department.

(3) An ambulatory surgical center.

~~(4) An end-stage renal disease facility.~~

~~(5)~~

A comprehensive outpatient rehabilitation facility that is certified to participate either in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, or the medicaid program under Title XIX (42 U.S.C. Sec. 1396 et seq.) of the federal Social Security Act, or both.

(d) Notwithstanding paragraph (2) of subdivision (c), the department shall retain the authority to inspect a primary care clinic pursuant to Section 1227, or as necessary to ensure the quality of care being provided.

SEC. 10. Nothing in this act is intended to affect health facilities licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code.

SEC. 11. The State Department of Public Health shall issue regulations necessary to implement this act no later than 180 days following its effective date.

SEC. 12. Pursuant to subdivision (c) of Section 10 of Article II of the California Constitution, this Act may be amended either by a subsequent measure submitted to a vote of the people at a statewide election; or by a statute validly passed by the Legislature and signed by the Governor, but only to further the purposes of the Act.

SEC. 13. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

October 13, 2017
Initiative 17-0015 (Amdt. #1)

The Attorney General of California has prepared the following title and summary of the chief purpose and points of the proposed measure:

AUTHORIZES STATE REGULATION OF KIDNEY DIALYSIS CLINICS. ESTABLISHES MINIMUM STAFFING REQUIREMENTS AND LIMITS CHARGES FOR PATIENT CARE. INITIATIVE STATUTE. Establishes minimum staffing requirements for nurses, technicians, and other staff at outpatient kidney dialysis clinics and sets minimum transition time between patients. Limits amounts clinics may charge for patient care and imposes penalties for excessive charges. Requires annual inspections and reporting to the state regarding clinic costs, patient charges, revenue, staffing ratios, and transition times between patients. Authorizes investigations and imposes fines for violations. Prohibits clinics from discriminating against patients based on the source of payment for care. Summary of estimate by Legislative Analyst and Director of Finance of fiscal impact on state and local government: **State administrative costs of around $10 million annually to be covered by increases in license fees on chronic dialysis clinics. State and local government savings associated with reduced government employee and retiree health benefits spending on dialysis treatment, potentially up to tens of millions of dollars annually. Net state government costs for Medi-Cal, potentially in the low tens of millions of dollars annually in the long run.** (17-0015.)

ALEX PADILLA
California Secretary of State

AP17:081

FOR IMMEDIATE RELEASE
October 13, 2017
CONTACT:
Jesse Melgar or Sam Mahood
(916) 653-6575

Proposed Initiative Enters Circulation

Authorizes State Regulation of Kidney Dialysis Clinics. Establishes Minimum Staffing Requirements and Limits Charges for Patient Care. Initiative Statute.

SACRAMENTO – Secretary of State Alex Padilla announced the proponent of a new initiative was cleared to begin collecting petition signatures today.

The Attorney General prepares the legal title and summary that is required to appear on initiative petitions. When the official language is complete, the Attorney General forwards it to the proponent and to the Secretary of State, and the initiative may be circulated for signatures. The Secretary of State then provides calendar deadlines to the proponent and to county elections officials. The Attorney General's official title and summary for the measure is as follows:

> **AUTHORIZES STATE REGULATION OF KIDNEY DIALYSIS CLINICS. ESTABLISHES MINIMUM STAFFING REQUIREMENTS AND LIMITS CHARGES FOR PATIENT CARE. INITIATIVE STATUTE.** Establishes minimum staffing requirements for nurses, technicians, and other staff at outpatient kidney dialysis clinics and sets minimum transition time between patients. Limits amounts clinics may charge for patient care and imposes penalties for excessive charges. Requires annual inspections and reporting to the state regarding clinic costs, patient charges, revenue, staffing ratios, and transition times between patients. Authorizes investigations and imposes fines for violations. Prohibits clinics from discriminating against patients based on the source of payment for care. Summary of estimate by Legislative Analyst and Director of Finance of fiscal impact on state and local government: **State administrative costs of around $10 million annually to be covered by increases in license fees on chronic dialysis clinics. State and local government savings associated with reduced government employee and retiree health benefits spending on dialysis treatment, potentially up to tens of millions of dollars annually. Net state government costs for Medi-Cal, potentially in the low tens of millions of dollars annually in the long run.** (17-0015.)

The Secretary of State's tracking number for this measure is 1811 and the Attorney General's tracking number is 17-0015.

The proponent of the measure, BJ Chisholm, must collect the signatures of 365,880 registered voters (five percent of the total votes cast for Governor in the November 2014 general election)

in order to qualify it for the ballot. The proponent has 180 days to circulate petitions for the measure, meaning the signatures must be submitted to county elections officials no later than April 11, 2018. The proponent can be reached (415) 421-7151 or bchisholm@altber.com.

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LAO

September 28, 2017

Hon. Xavier Becerra
Attorney General
1300 I Street, 17th Floor
Sacramento, California 95814

Attention: Ms. Ashley Johansson
Initiative Coordinator

Dear Attorney General Becerra:

Pursuant to Elections Code Section 9005, we have reviewed the proposed statutory initiative regarding staffing and pricing requirements for kidney dialysis providers (A.G. File No. 17-0015 Amendment No. 1).

BACKGROUND

Chronic Dialysis Clinics

End Stage Renal Disease (ESRD) Is the Final Stage of Chronic Kidney Disease. Patients suffering from ESRD, the fifth and final stage of kidney disease, must receive kidney dialysis (or a kidney transplant) to survive. Kidney dialysis artificially mimics what healthy kidneys do—filtering out waste and toxins from the blood supply, either outside the body (hemodialysis) or inside the body (peritoneal dialysis). Peritoneal dialysis is typically conducted every day at the patient's home, whereas hemodialysis is typically administered at a clinic three times per week with each treatment lasting between three and four hours.

Many ESRD Patients Treated at Chronic Dialysis Clinics (CDCs). Although ESRD patients can receive hemodialysis treatments at hospitals or in their own homes, many receive treatments at CDCs. In California, about 650 CDCs serve more than 66,000 ESRD patients. While CDCs are sometimes owned and operated by private nonprofit or public entities, two private for-profit entities—DaVita Healthcare Partners and Fresenius Medical Care—and their CDCs treat the vast majority of ESRD patients in California.

Department of Public Health (DPH) Licenses and Inspects CDCs. DPH is responsible for licensing CDCs and conducting federal certification surveys for the Centers for Medicare and Medicaid Services (CMS). (While a license is issued to a CDC, the CDC itself may be owned or operated by a person, corporation, or other entity—referred to as a "governing entity" in this measure.) Through the federal certification process, DPH conducts inspections of each CDC about once every three years. DPH has not promulgated regulations for CDCs and currently follows federal certification standards for state licensing activities. It lacks the authority to

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impose penalties on CDCs that fail to comply with certification standards. DPH is also responsible for certifying hemodialysis technicians who work with nurses to carry out hemodialysis treatments, including inserting needles to draw and replace blood and monitoring patients' vital signs.

State Does Not Set Minimum Staffing Requirements. Currently, there are no federal or state minimum staffing requirements for CDCs, though federal regulations require an "adequate number" of qualified personnel (including direct care staff such as registered nurses) be present to maintain "appropriate" patient-to-staff ratios.

State Follows Federal Guidance on Patient Transitions. Through its inspections of CDCs, DPH monitors compliance with recent CMS requirements about patient transitions (time between patients) at dialysis stations. CMS based the new requirements on a recommendation from the federal Centers for Disease Control and Prevention that to avoid cross contamination, a patient must have completely vacated a dialysis treatment station before the station is cleaned, disinfected, and prepared for the next patient. There are currently no state or federal rules specifying a minimum amount of time for transitions.

CDCs Receive Compensation for Treatment From Various Payers. CDCs receive payments for their services from patients and third-party payers. Third-party payers pay CDCs (the second party) for services delivered to patients (the first party). Below, we describe the third-party payers that account for the greatest volume of patients treated and amount of revenues received by CDCs.

Government Programs

Federal, state, and local government programs provide health care benefits to certain eligible populations. The two largest government programs for outpatient dialysis services in terms of patient volume and spending are Medicare and Medi-Cal, as described below.

Medicare. This is the federally funded program that provides coverage to most individuals 65 and older and certain younger persons with disabilities. Individuals with ESRD who need regular dialysis are eligible for Medicare coverage at any age if they, their spouse, or (if a dependent child) either of their parents meet certain work requirements. Medicare coverage for individuals with ESRD typically starts three months after dialysis begins. During this three-month "waiting period," an individual's other health insurance coverage—such as an employer group health plan or Medicaid—pays for the individual's dialysis. Once Medicare coverage starts, Medicare becomes the primary payer for dialysis except for individuals covered under an employer or union group health plan. (We discuss this exception in the commercial health insurers section below.) Medicare is the primary payer for the majority of patients receiving treatment at CDCs.

Medi-Cal. In California, the federal-state Medicaid program, known as Medi-Cal, provides health care services to low-income Californians. The costs of the Medicaid program are generally shared between states and the federal government, and the percentage of Medi-Cal costs paid by the federal government varies depending on the enrollee and/or service. For Medi-Cal beneficiaries with ESRD who are also eligible for Medicare—dual eligibles—Medicare is the primary payer for dialysis (after the three-month waiting period) and Medi-Cal is the secondary payer. Medicare covers 80 percent of the costs of outpatient dialysis services for dual

eligibles, and Medi-Cal covers the remaining 20 percent. Medi-Cal also covers any Medicare premiums, deductibles, or other costs that otherwise would be paid by the dual eligible. For Medi-Cal beneficiaries with ESRD who are not eligible for Medicare—non-dual eligibles—Medi-Cal is the sole payer for dialysis.

Medi-Cal Delivery Systems. Medi-Cal provides health care services through two main delivery systems: fee-for-service (FFS) and managed care. In the FFS system, a health care provider receives an individual payment for each medical service delivered to a beneficiary. Most dual eligibles receive dialysis through the Medi-Cal FFS system. In the managed care system, Medi-Cal generally contracts with managed care plans to provide health care for beneficiaries enrolled in these plans. Managed care enrollees may obtain services from providers—including CDCs—that accept payments from the plans. The plans are paid a predetermined amount per enrollee, per month (known as a capitation payment) regardless of the number of services each enrollee actually receives. Some Medi-Cal managed care plans are administered by government entities such as counties, whereas other plans are operated by commercial health insurers that contract with Medi-Cal. Most non-dual eligibles receive dialysis through the Medi-Cal managed care system.

Major Risk Medical Insurance Program (MRMIP). The MRMIP provides health insurance coverage to individuals who, prior to the Patient Protection and Affordable Care Act (ACA), could not obtain coverage or were charged unaffordable premiums in the individual health insurance market because of their preexisting conditions. Given the ACA's prohibition on health plans denying coverage to individuals based on preexisting conditions, most MRMIP enrollees can now obtain other coverage. A few individuals with ESRD, however, remain enrolled in MRMIP because, for example, they are ineligible for other coverage based on their immigration status.

Commercial Health Insurers

Commercial health insurers provide coverage to members of employer groups, organizations, or individuals who purchase health insurance. These insurers receive a premium in exchange for covering an agreed-upon set of health care services.

Commercial Health Insurers and Medicare. During Medicare's three-month waiting period, an individual's other health insurance coverage pays for dialysis. After the waiting period, if an individual is covered under an employer or union group health plan, the plan must continue to pay for dialysis as the primary payer (with Medicare as the secondary payer) for another 30 months. These additional 30 months are referred to as a "coordination period." After this coordination period, Medicare becomes the primary payer and the employer or union group health plan becomes the secondary payer.

Health Benefits for State and Local Government Employees and Retirees. The state, California's two public university systems, and many local governments in California provide health benefits for their employees and related family members and for some of their retired workers. Typically, state and local governments contract with commercial health insurers to cover health care services. Together, state and local governments pay tens of billions of dollars for employee and retiree health benefits each year.

Rates Paid by Commercial Health Insurers Significantly Exceed Rates Paid by Government Programs

Government Program Rates Are Primarily Set Through Medicare. Outpatient dialysis rates for government programs are primarily set by CMS in Medicare. Dialysis providers cannot directly negotiate higher rates from CMS. Because Medi-Cal FFS rates for outpatient dialysis provided to dual eligibles are based on Medicare rates, these rates are also not subject to negotiation. CDCs and governing entities can, however, negotiate higher rates from Medi-Cal managed care plans serving non-dual eligibles. In many cases, Medi-Cal managed care plans base their rates on Medi-Cal FFS rates (and thus on Medicare rates), but in some cases will pay providers higher rates depending on a provider's availability in a given service area in order to maintain access to services needed for their beneficiaries.

Commercial Rates Are Negotiated Between Insurers and Providers. Outpatient dialysis rates for commercial health insurers are set through negotiations between the commercial health insurers and CDCs' governing entities. Depending on the governing entity's market power, the entity can potentially negotiate rates that are much higher than the Medicare rates.

Relative to Patients Covered, Commercial Health Insurers Represent a Disproportionate Share of CDC Revenue. For example, based on financial information from one major governing entity in the state, commercial health insurers account for about one-tenth of this particular governing entity's patients and treatments, but generate about one-third of the governing entity's total annual revenues. (CDCs receive a significant portion of their revenues during the 30-month coordination period when an employer or union health plan is the primary payer for dialysis services and Medicare is the secondary payer.) Government programs, on the other hand, account for about nine-tenths of the governing entity's patients and treatments, but generate only two-thirds of its total annual revenues. We estimate that commercial health insurers, on average, pay multiple times what government programs pay for outpatient dialysis services.

PROPOSAL

Places New Operational Requirements on CDCs

Sets Minimum Direct Care Staffing Requirements. This measure requires CDCs to have at least one registered nurse for every eight patients and at least one certified hemodialysis technician for every three patients. The measure also requires CDCs to ensure the patient caseloads of a full-time equivalent social worker or dietician does not exceed 75. Staffing requirements would take effect March 31, 2019.

Establishes Minimum Transition Times. This measure would require that the transition time between patients at a dialysis treatment station be at least 45 minutes, unless DPH can demonstrate with clinical evidence why a shorter amount of time would be sufficient. Requirements about minimum transition times would take effect March 31, 2019.

Requires Annual Inspections by DPH. This measure requires DPH to conduct inspections of each CDC at least annually, and as often as necessary, to ensure compliance with hygiene and sanitation protocols, compliance with the staffing and transition time requirements of this measure, and adequacy of the quality of patient care.

Requires Quarterly Reporting. This measure requires CDCs to provide information about actual staffing ratios and transition times to DPH at least four times per year, including: (1) the daily total number of hours and actual hours worked by nurses and hemodialysis technicians, (2) the daily total number of patients and actual hours they received direct care, (3) the daily average transition time for each dialysis station, and (4) the weekly number of full-time equivalent social workers and registered dieticians and their patient caseload numbers. The report must also include information about any instances in which the CDC was out of compliance with this measure and the reasons for noncompliance.

Requires Timely Investigation of Complaints. This measure requires DPH to investigate complaints about violations of this measure's provisions within 60 days and specifies that the complaints can come from a patient, a patient's family member, or an association of patients; an employee or association of employees; a vendor; or a contractor. If the investigation reveals that a CDC was in violation of the provisions, the measure requires DPH to assess an appropriate penalty (as specified below).

Establishes Penalty Structure. This measure requires DPH to promulgate regulations about the criteria to be used to assess administrative penalties against CDCs that have violated provisions of this measure. It stipulates the criteria should include, at a minimum, consideration of patient risks, actual harm to patients, the severity of the violation, the CDC's history of compliance with regulations, whether it had any control over the violation, whether it willfully committed the violation, and whether it acted quickly to remedy a known violation. The measure allows DPH to assess administrative penalties (which a CDC may contest by requesting a hearing) as follows:

- Up to $100,000 for major violations,
- Up to $20,000 for intermediate violations, and
- Up to $2,000 for minor violations.

Beginning January 1, 2019, and up until DPH has promulgated its penalty regulations described above, DPH can assess penalties of up to $100,000 for violations that put patients in immediate jeopardy of serious injury or death.

Limits, in Effect, Prices Clinics May Charge Commercial Health Insurers

Requires Rebates to Commercial Health Insurers When Total Revenues Exceed Specified Cap. Beginning in 2019, the measure requires each governing entity to annually calculate the amount by which total dialysis treatment revenues in all of its clinics exceed a cap equal to 115 percent of certain specified costs for direct patient care plus certain specified costs related to treatment quality (such as health information technology or clinic staff training). The measure then requires the governing entity or its CDCs to annually distribute rebates that equal the amount by which total treatment revenues exceed the cap. The measure specifies that Medicare and other federal, state, or local government payers would not receive rebates, such that rebates would be primarily paid to commercial health insurers. There is some uncertainty as to whether commercial plans that contract with state and local governments to provide health benefits (such as plans that cover employees and retirees or Medi-Cal beneficiaries in the managed care

delivery system) would be eligible for rebates under the initiative. This is because the commercial plans are providing services on behalf of a government entity, but they are themselves private entities and are financially responsible for paying for the services. Whether these commercial plans would be eligible for rebates will depend on how the measure is implemented. Rebates would be allocated to each commercial health insurer proportional to the amount initially paid for dialysis treatment. By requiring rebates to in the event that total revenues exceed the cap, the measure would effectively limit the average rate CDCs and their governing entities may charge commercial health insurers.

In the event that a governing entity or its CDCs are required to provide a rebate, the measure further requires the governing entity to pay interest on the rebate to the payer (calculated from the date that the initial payment for treatment was made) and a penalty to DPH in the amount of 5 percent of the amount of the rebates (up to a maximum of $100,000), the proceeds of which would go to fund DPH's costs to administer the functions required in the measure.

Outlines Legal Process for Revenue Cap to Be Raised in Certain Circumstances. The measure envisions the possibility that a CDC or governing entity might bring a legal challenge against the measure's rebate provisions on the basis that, for a particular fiscal year, requiring the payment of rebates amounts to an unconstitutional taking of private property without due process or just compensation. In the event that such a challenge is successful, the measure requires that the rebate provisions would still apply, but only after the court replaces the measure's revenue cap with the lowest possible alternative revenue cap (a ratio of specified direct patient care and quality costs higher than 115 percent) that would not be unconstitutional. The measure places the burden on the challenging CDC or governing entity to propose the alternative revenue cap.

Requires Annual Reporting. This measure requires governing entities to prepare annual reports relative to the rebate provisions and to submit them to DPH for each fiscal year starting on or after January 1, 2019. These reports are to list the number of treatments provided, the amount of direct care and quality improvement costs, the amount of the governing entity's revenue cap, the amount by which revenues exceeded the cap, and the amounts of rebates provided to various payers. The DPH may assess penalties of up to $100,000 if a governing entity fails to maintain required reporting information, fails to submit reports in a timely manner, inaccurately reports information about treatment costs, or fails to justify why rebates were not issued in a timely manner. Any resulting penalty funds must be used by DPH for the implementation and enforcement of laws concerning CDCs.

FISCAL EFFECTS

State Agency Administrative Costs

The measure imposes new administrative, regulatory, oversight, and workload responsibilities on DPH. Although the total cost to comply with these new duties is likely around $10 million annually, the measure requires DPH to adjust the annual license fee paid by CDCs, which is currently set at $3,407 per facility, to cover these costs. Some implementation and enforcement costs would be offset by penalties assessed on CDCs or their governing entities for failing to comply with reporting requirements, but the amount of this offset is unknown.

Fiscal Impact Depends on CDC's Response to Measure's Requirements

Staffing Ratios and Transition Time Requirements Would Increase CDC Costs. While we do not have comprehensive data on current staffing levels or transition times at CDCs in California, it appears that many CDCs are not currently meeting staffing ratio and transition time requirements in the measure. For these entities, coming into compliance with the measure's requirements would involve hiring additional staff, expanding hours of operation, and acquiring additional treatment stations, which would increase these CDCs' operating costs.

Various Potential Responses to Rebate Provisions. Based on our research into the operations of major dialysis governing entities, many CDCs and governing entities have revenues that exceed the measure's 115 percent revenue cap and, as such, we expect the rebate provisions in the measure would apply under existing revenue and cost structures. However, the effect of the measure on CDC operations—and ultimately on state and local government finances—would depend on how, if at all, CDCs change operations in response to the measure to avoid having to pay rebates. Some potential behavioral responses to the rebate provisions are:

- ***Modify Revenue and Cost Structures.*** In order to avoid paying rebates (and the accompanying 5 percent penalty on the amount of rebates) CDCs and governing entities would likely modify their revenue and cost structures. For example, CDCs and governing entities could charge lower rates to commercial health insurers in order to bring total revenue below the cap. CDCs and governing entities could also modify their cost structures to increase the portion of their costs that count toward setting the revenue cap. For example, CDCs and governing entities could increase spending on direct services and specified quality improvement items while reducing overhead and management costs that are not counted toward determining the revenue cap. This would increase the revenue cap and the effective rates that could be charged to commercial health insurers without triggering rebates for those CDCs and governing entities.
- ***Seek Adjustments to the Revenue Cap.*** In instances where CDCs believe they cannot achieve a reasonable return on their operations, they may choose to challenge the application of the rebate provisions in court. If such challenges proceed as the measure envisions, successful challenges could result in higher revenue caps for some CDCs in some years.
- ***Cease Operations.*** Finally, reduced revenues under the rebate provisions would decrease incentives for CDCs and their governing entities to participate in the market. CDCs and governing entities in some cases may decide to cease operations if reduced revenues under the rebate provisions do not provide sufficient inducement to remain in the market.

Fiscal Impact of Various Behavioral Responses

Potential Savings to State and Local Governments Providing Employee Health Coverage. Commercial health insurers that provide health benefits for state and local government employees—if they are considered eligible under the measure—would likely pay lower rates for dialysis treatment, either through receiving rebates or by negotiating lower prices (since CDCs

and governing entities would have an incentive to negotiate rates low enough to avoid having to pay a penalty of 5 percent of the rebated amount). The extent to which commercial health insurers pay lower rates would depend on how CDCs and governing entities respond to the provisions of the measure. For example, reductions in commercial health insurer rates would be partially offset to the extent that CDCs and governing entities increase spending on direct services and quality improvements in order to comply with the measure's requirements. How much these lower rates might reduce health insurance premiums paid by state and local governments for their employees is uncertain. For example, commercial health plans that contract with the California Public Employees' Retirement System (CalPERS)—which provides health coverage to state employees, some local government employees, retirees, and their families—paid about $70 million for dialysis services in 2016 (for enrollees for which the CalPERS plan was the primary payer). We assume that there could be a significant reduction in these costs under the initiative. Some portion of these savings could be retained by the health plans, with the remainder of the savings passed on as reductions in employer health insurance premiums paid by state and local governments. Given these assumptions—as well as the number of commercial health insurers who provide health benefits for local government and school district employees that do not participate in CalPERS—we estimate that state and local governments could potentially save up to tens of millions of dollars under this initiative.

Net State Government Costs for Medi-Cal. As discussed above, the initiative's staffing ratio and transition time requirements would increase operating costs for CDCs. Increased costs at CDCs could increase state costs in the Medi-Cal program, both in the short term and long term. In the short term, it is unclear to what extent, if at all, potential increases in CDC operating costs would ultimately be reflected in Medicare and Medi-Cal FFS rates. As noted previously, CDCs and governing entities do not directly negotiate rates with Medicare, and Medi-Cal FFS rates (for dual eligibles) are based on Medicare rates. Most non-dual eligibles with ESRD, however, receive dialysis through Medi-Cal managed care. CDCs with increased operating costs could charge higher rates to Medi-Cal managed care plans, and plans' higher costs could ultimately be reflected in higher capitation payments from the state. Non-dual eligibles with ESRD, however, are a small population within Medi-Cal managed care. Commercial Medi-Cal managed care plans' higher costs could also be offset somewhat—either through receiving rebates or negotiating lower prices with providers—if such plans are considered eligible for rebates under this measure. To the extent such commercial plans do receive rebates or negotiate lower prices, there could be modest offsetting savings to the Medi-Cal program. Over the long term, increased costs for CDCs could put upward pressure on Medicare rates. To the extent that Medicare rates are adjusted upward to reflect increased costs, the state would eventually have increased costs for dual eligibles with ESRD in the Medi-Cal FFS delivery system. We estimate that total net state costs could be in the low tens of millions of dollars annually in the long run.

Highly Uncertain Fiscal Effects From Potential Changes in Quality and Availability of Treatment. Depending on how CDCs respond to the measure, the quality and availability of dialysis treatment in California could change, with potential fiscal effects on state and local governments. For example, it is possible that the staffing and transition time requirements imposed by the measure could improve the overall quality of dialysis treatment in the state and result in an improvement in health outcomes for dialysis patients, such as reduced

hospitalizations. To the extent that the requirements of the measure reduce dialysis patients' need for health care services beyond dialysis treatment, state and local government costs related to health care (including costs to provide health care to employees and retirees or costs to fund Medi-Cal and other state programs that provide health coverage for certain California residents) could be reduced. On the other hand, if CDCs collectively reduce operations in the state as a result of the measure's requirements, the availability of outpatient dialysis services might be reduced. In that case, patients might seek dialysis treatment in more expensive inpatient settings or could require additional treatment related to not having timely access to dialysis treatment. This could potentially result in higher state and local government costs related to health care. Whether these effects would ultimately materialize or what their potential magnitude would be are highly uncertain.

Summary of Fiscal Effects

We estimate that the measure would have the following major fiscal impacts:

- State administrative costs of around $10 million annually to be covered by increases in license fees on chronic dialysis clinics.
- State and local government savings associated with reduced government employee and retiree health benefits spending on dialysis treatment, potentially up to tens of millions of dollars annually.
- Net state government costs for Medi-Cal, potentially in the low tens of millions of dollars annually in the long run.

Sincerely,

for Mac Taylor
Legislative Analyst

For Michael Cohen
Director of Finance